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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,538	08/16/2006	Klaus Abraham-Fuchs	32860-001070/US	8501

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EXAMINER	
WINSTON III, EDWARD B	
ART UNIT	PAPER NUMBER
3686	

NOTIFICATION DATE	DELIVERY MODE
03/03/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/589,538	ABRAHAM-FUCHS ET AL.	
	Examiner	Art Unit	
	EDWARD WINSTON	3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. The following Office action in response to communications received March 11, 2010. Claims 1,7, 16-20 have been amended. Therefore, claims 1-20 are pending and addressed below.

2. Applicant's amendments to the claims are sufficient to overcome the 35 USC § 101 and 35 USC § 102(e) rejections set forth in the previous office action dated December 24, 2009.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham **v.** John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7 and 10-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Sabol et al. (US 2004/0122719) in view of Urquhart et al. (US 2004/0073454).

CLAIM 1.

Sabol et al. teaches a method for determining a degree of compliance with a performance specification assigned to a medical working practice, the method comprising:

- recording and storing, by a data-processing device, data correlated with the medical working practice; (see at least Paragraph 0008)
- storing, by a test system, test criteria for the data, correlated with the performance specification; reading, via the test system, the data stored in the data-processing device; As stated in Paragraph [0019] of Applicants Summary, the degree of compliance may moreover lead to a simple Yes/No decision, i.e. compliance or noncompliance with the performance specification. (see at least Paragraph 0332 wherein, provided are structured video and/or audio recordings of questions and answers; Figures 1-31 Paragraph 0004 and 0008)

Sabol et al. does not explicitly teach a method for evaluating, via the test system, the data with the aid of the test criteria and determining the degree of compliance with the performance specification. It would have been obvious to one of ordinary skill in the art at the time of the invention to expand the method of Sabol et al. to include event monitoring devices that are helpful in reporting to the physician the dosing history of a patient, from which the patient's

degree of compliance with the prescribed drug regimen can be determined (see at least Paragraph 0004) as taught by Urquhart et al. One of ordinary skill in the art at the time of the invention would have been motivated to expand the process of Sabol et al. in this way since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

CLAIM 2.

Sabol et al. teaches a method as claimed in claim 1, wherein:

- clinical data are collected as the medical working practice, the collection process being assigned a collection protocol (Acquisition techniques) as the performance specification (see at least Figures 1-31 Paragraph 0004 and 0008).

CLAIM 3.

Sabol et al. teaches a method as claimed in claim 2, wherein:

- a measurement value for a clinical study is collected from a patient as the medical working practice, and the test system sends the measurement value as a valid measurement value to a study database if the collection protocol is complied with (see at

least Figures 1-31 Paragraph 0004 and 0008).

CLAIM 4.

Sabol et al. teaches a method as claimed in claim 1, wherein:

- a knowledge-based system is used as the test system, and the performance specification is stored in the form of a rule set in the knowledge-based system (see at least Paragraph 0075 Figures 5[62-74]; Paragraph 0306).

CLAIM 5.

Sabol et al. teaches a method as claimed in claim 4, wherein:

- the performance specification is stored as a module in the rule set (see at least Paragraph 0075 Figures 5[62-74]; Paragraph 0306).

CLAIM 6.

Sabol et al. teaches a method as claimed in claim 1, wherein:

- the method is carried out automatically after each medical working practice (see at least Paragraph 0288)

CLAIM 7.

Sabol et al. teaches a method as claimed in claim 1, wherein:

- if the performance specification is not complied with, a decision is made as to whether it is possible to repeat the working practice and, if so, repetition is requested; and if repetition is possible, a corresponding repetition request is made (see at least Paragraph 0294).

Sabol et al. does not expressly teach the specific data recited in claims 7. These differences are only found in the non-functional descriptive material and are not functionally involved in the manipulative steps of the invention nor do they alter the recited structural elements; therefore, such differences do not effectively serve to patentably distinguish the claimed invention over the prior art. The manipulative steps of the invention would be performed the same regardless of the specific data. Further, the structural elements remain the same regardless of the specific data. Thus, this descriptive material will not distinguish the claimed invention from the prior art in terms of patentability as the claimed invention fails to present a new and unobvious functional relationship between the descriptive material and the substrate, see In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983); In re Lowry, 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir. 1994)); In re Ngai, 367 F.3d 1336, 1336, 70 USPQ2d 1862, 1863-64 (Fed. Cir. 2004); MPEP § 2106.

CLAIM 10.

Sabol et al. teaches a method as claimed in claim 8, wherein:

- the performance specification is stored as a module in the rule set.

  (see at least Paragraph 0020)

Examiner notes that module has not been explicitly explained in applicants Detailed Specification. Therefore, using the broadest reasonable interpretation module is considered to be a program or software which is not patentable under **35 USC § 101**. Refer to MPEP.

CLAIM 11.

Sabol et al. teaches a method as claimed in claim 9, wherein:

- the performance specification is stored as a module in the rule set.

  (see at least Paragraph 0020)

Examiner notes that module has not been explicitly explained in applicants Detailed Specification. Therefore, using the broadest reasonable interpretation module is considered to be a program or software which is not patentable under **35 USC § 101**. Refer to MPEP.

CLAIMS 12-15.

Sabol et al. teaches a method as claimed in claims (2-5) wherein:

- the method is carried out automatically after each medical working practice.

CLAIMS 16 – 20.

Claim 16-20 is directed to a method for determining a degree of compliance with a performance specification assigned to a medical working practice. Claim 16-20 recites the same or similar limitations as those addressed above for Claim 7. Claim 16-20 is therefore rejected for the same reasons as set forth above for Claim 7 respectively.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham **v.** John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8-9 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Sabol et al. (US 2004/0122719) in view of Urquhart et al. (US 2004/0073454) further in view of Miller et al. (US 5,446,653).

CLAIMS 8 & 9.

Sabol et al. further teach(s) a method as claimed in claim 2 & 3, wherein:

- a knowledge-based system is used as the test system (see at least Figure 10-14[136])

Sabol et al. does not explicitly teach a method as in claims 2 & 3 wherein the performance specification is stored in the form of a rule set in the knowledge-based system. It would have been obvious to one of ordinary skill in the art at the time of the invention to expand the method of Sabol et al. to include documents that are automatically generated by assembling a plurality of clauses selected from a library of clauses stored in a computer system. A rule set is assigned to each of the clauses. Each rule set provides at least one rule that must be satisfied in order to include the clause associated therewith in a document (see at least Abstract) as taught by Miller et al. One of ordinary skill in the art at the time of the invention would have been motivated to expand the process of Sabol et al. in this way since all the claimed elements were

known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Response to Arguments

Applicant's arguments filed March 11, 2010 have been fully considered but they are not persuasive. In the remarks applicant argues (1) Sabol fails to determine a degree of compliance with performance specification. Therefore, Sabol fails to disclose or suggest the evaluating "data with the aid of the test criteria and determining the degree of compliance with the performance specification," as set forth in claim 1.

In response to argument (1), Examiner respectfully disagrees. In previous office action, Examiner sited Paragraph [0019] of Applicants Summary. It states that the degree of compliance may moreover lead to a simple Yes/No decision, i.e. compliance or noncompliance with the performance specification. In Paragraph [0289] Sabol teaches a logic engine that essentially contains the rules that coordinate the various functions carried out by the system. Such coordination includes accessing and storing data in the knowledge base, as well as execution of various computer-assisted data operating algorithms, such as for feature detection, diagnosis (testing), acquisition, processing and decision-support (determine a degree of compliance). The

logic engine can be rule-based, and may include a supervised learning or unsupervised learning system.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Padron et al. (US 2003/0135394) Health Service Delivery System with Incentives.

Applicant's amendment necessitated any new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EDWARD WINSTON whose telephone number is (571) 270-7780. The examiner can normally be reached on MONDAY-THURDAY; 9:00AM-6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/E. W./
Examiner, Art Unit 3686
23 February 2011

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686